

**REMARKS**

Favorable reconsideration of this application, in light of the preceding amendments and following remarks, is respectfully requested.

Claims 24-37, 39-40 and 46-65 are pending in this application. Claim 24 is amended and claim 65 is added. Support for the amendment to claim 24 and the addition of claim 65 can be found on page 39, line 5 – page 40, line 16 of the as filed specification. Claims 24 and 46 are the independent claims.

Applicants note with appreciation the Examiner's acknowledgement that certified copies of all priority documents have been received by the U.S.P.T.O. Action, summary at 12. Applicants also respectfully note the present action indicates that the drawings have been accepted by the Examiner. Action, summary at 10.

**Sequence Compliance and Specification Objections**

The application is objected to because it does not include a statement that the sequence listing includes no new matter. Applicants have included a Statement with the filing of this response. The disclosure is objected to for informalities. Applicants have made the required changes above. Therefore, withdrawal of the objections to the application and disclosure is respectfully requested.

**Rejections under 35 U.S.C. § 102**

***Rasochova***

Claims 24-29, 31, 32, 37, 39 and 40 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Publication No. 2003/0074677 to Rasochova et al. (hereinafter “Rasochova”). Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that, regarding claim 24, Rasochova et al teach a DNA molecule comprising cDNA of an RNA virus vector that has been constructed by inserting an exogenous RNA component and a ribozyme sequence at the 3' region; and that Rasochova et al teach the DNA Molecule where the exogenous RNA component has a coding function in which the RNA acts as a messenger RNA, encoding a sequence which, when translated by the host cell, results in the synthesis of a peptide or protein. Applicants respectfully disagree.

Applicants submit that Rasochova does not teach or suggest “cDNA of a virus vector that has been constructed by inserting a coding gene of an arbitrary protein into an RNA virus” as recited in independent claim 24. Rather, Rasochova teaches a DNA-launching platform encoding a modified viral RNA molecule including an RNA viral component attached to an exogenous RNA component.

Furthermore, Rasochova does not teach or suggest “a ribozyme sequence ligated to the 3' end of the virus vector cDNA” as recited in independent claim 24. Rather, Rasochova teaches a nucleotide sequence

encoding a self-cleavable ribozyme situated proximate to the 3' end of said RNA molecule.

The Applicants, therefore, respectfully request that the rejection to Claim 24 under 35 U.S.C. § 102(b) be withdrawn.

Claims 25-29, 31, 32, 37, 39-40 and newly added claim 65, dependent on independent claim 24, are patentable for the reasons stated above with respect to claim 24 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 24 and all claims dependent thereon.

***Mori***

Claims 24-26, 30, 31, 37, 39 and 40 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Mori et al. (hereinafter "Mori"), Plant Journal, Vol. 27, No. 1, pp. 79-86 (2001). Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that, regarding claim 24, Mori et al teach a DNA fragment comprising a cDNA of a Brome mosaic virus that has been constructed by inserting a coding sequence of a human gamma interferon (IFN) protein into the RNA virus, and ligating a ribozyme sequence to the 3' end of the virus vector cDNA. Applicants respectfully disagree.

Applicants submit that Mori does not teach or suggest "cDNA of a virus vector that has been constructed by inserting a coding gene of an

arbitrary protein into an RNA virus" as recited in independent claim 24. Rather, Mori teaches inserting a RNA1-cDNA fragment into a binary transformation vector.

The Applicants, therefore, respectfully request that the rejection to Claim 24 under 35 U.S.C. § 102(b) be withdrawn.

Claims 25-26, 30, 31, 37, 39-40 and newly added claim 65, dependent on independent claim 24, are patentable for the reasons stated above with respect to claim 24 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 24 and all claims dependent thereon.

### **Rejections under 35 U.S.C. § 103**

#### ***Mori in view of Zuo***

Claims 33-36 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mori et al. in view of U.S. Patent No. 6,452,068 to Zuo et al. (hereinafter "Zuo"). Applicants respectfully traverse this rejection for the reasons detailed below.

Even assuming *arguendo* that Zuo could be combined with Mori (which Applicants do not admit), the Examiner has failed to show how Zuo remedies the deficiencies of Mori with respect to independent claim 24. Thus, claims 33-36 are patentable over Mori and Zuo for the reasons set forth above with respect to independent claim 24.

The Applicants, therefore, respectfully request that the rejection to Claims 33-36 under 35 U.S.C. § 103(a) be withdrawn.

***Mori in view of David***

Claims 46-48, 50, 51, and 55-64 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mori in view of David et al. (hereinafter “David”), Plant Physiology, Vol. 125, pp. 1548-1553, April 2001. Applicants respectfully traverse this rejection for the reasons detailed below.

The Office Action stated that Mori et al teach a process for producing a transformant for protein production, comprising (i) transforming *N. benthamiana* host cells with a GVG transcription factor expressing DNA fragment in which the GVG coding sequence is operably linked to the CaMV 35S promoter; where transforming is done by an Agrobacterium method (ii) screening the transformants obtained in step (i) for an individual FO plant expressing GVG; and (iii) crossing the FO GVG-expressing plants with 2FR plants containing eDNA of a virus vector that has been constructed by inserting a coding gene of human gamma interferon (IFN) into an RNA virus, where the IFN coding sequence is ligated to the 6XUASGal4 inducible promoter, which is induced by the GVG transcription factor; that production of transgenic plants containing eDNA of rNAI or cDNAs of both RNA2 and FCP2IFN, pages 82-83, Induced replication of FCP2IFN and sztbgenonzic n7RNA amplification in GVG1 x 2FR plants; page 85, Transformation of Nicotiana benthamiana; Figure 1; that specifically, the virus vector used in the in GVG1 x 2FR plants) to a single step based on the production of a single

vector containing all necessary elements of the inducible system, as taught by Zuo et al; and that, based upon the teachings of the cited references, the high skill of one of ordinary skill in the art, and absent any evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention. Applicants respectfully disagree.

Applicants submit that Mori does not teach or suggest "a second transforming step of transfecting the transformant, obtained in the screening step, with a protein-expressing DNA fragment in which cDNA of a virus vector that has been constructed by inserting a coding gene of an arbitrary protein into an RNA virus is ligated to an inducible promoter which is induced by the transcription factor" as recited in independent claim 46. Rather, as is stated above with reference to independent claim 24, Mori teaches inserting a RNA1-cDNA fragment into a binary transformation vector instead of constructing cDNA of a virus vector by inserting a coding gene of an arbitrary protein into an RNA virus.

The Applicants, therefore, respectfully request that the rejection to Claim 46 under 35 U.S.C. § 103(a) be withdrawn.

Claims 47-48, 50, 51, and 55-64, dependent on independent claim 46, are patentable for the reasons stated above with respect to claim 46 as well as for their own merits.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection to independent claim 46 and all claims dependent thereon.

***Mori in view of David and Zuo***

Claim 49 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Mori in view of David and further in view of Zuo. Applicants respectfully traverse this rejection for the reasons detailed below.

Even assuming *arguendo* that David and Zuo could be combined with Mori (which Applicants do not admit), the Examiner has failed to show how David and Zuo remedies the deficiencies of Mori with respect to independent claim 24. Thus, claim 49 is patentable over Mori and David and Zuo for the reasons set forth above with respect to independent claim 24.

The Applicants, therefore, respectfully request that the rejection to Claim 49 under 35 U.S.C. § 103(a) be withdrawn.

***Mori in view of David and Rasochova***

Claims 52-54 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Mori in view of David and further in view of Rasochova. Applicants respectfully traverse this rejection for the reasons detailed below.

Even assuming *arguendo* that David and Rasochova could be combined with Mori (which Applicants do not admit), the Examiner has failed to show how David and Rasochova remedy the deficiencies of Mori with respect to independent claim 46. Thus, claims 52-54 are patentable over Mori and David and Rasochova for the reasons set forth above with respect to independent claim 46.

The Applicants, therefore, respectfully request that the rejection to Claims 52-54 under 35 U.S.C. § 103(a) be withdrawn.

**CONCLUSION**

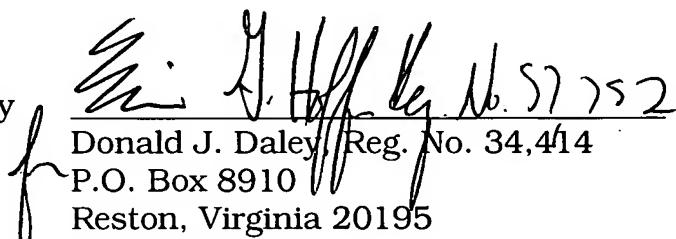
In view of the above remarks and amendments, the Applicants respectfully submit that each of the pending objections and rejections has been addressed and overcome, placing the present application in condition for allowance. A notice to that effect is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to contact the undersigned.

Should there be any outstanding matters that need to be resolved in the present application, the Examiner is respectfully requested to contact Erin G. Hoffman, Reg. No. 57,752, at the telephone number of the undersigned below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 08-0750 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

Respectfully submitted,

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Attachment: Supporting Statement for Sequence Listing